



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 721, and 725

[EPA-HQ-OPPT-2020-0588; FRL-8582-01-OCSPP]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (21-1.5e)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances that were the subject of premanufacture notices (PMNs) and a Microbial Commercial Activity Notice (MCAN). The SNURs require persons who intend to manufacture (defined by statute to include import) or process any of these chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the use, under the conditions of use for that chemical substance, within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required by that determination.

DATES: This rule is effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on **[INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4163; email address: wysong.william@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.*, chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import provisions promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and Orders under TSCA, which would include the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20 or 40 CFR 725.920 for the microorganism), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. How can I access the dockets?

The dockets include information considered by the Agency in developing the proposed and final rules. The docket for this action, identified by docket identification (ID) number EPA-

HQ-OPPT-2020-0588, is available online at <https://www.regulations.gov> and in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Background

A. What action is the Agency taking?

EPA is finalizing SNURs under TSCA section 5(a)(2) for certain chemical substances which were the subject of PMNs and an MCAN. Previously, in the *Federal Register* of June 11, 2021 (86 FR 31239) (FRL-10022-56), EPA proposed SNURs for these chemical substances and established the record for these SNURs in the docket under docket ID number EPA-HQ-OPPT-2020-0588. That docket includes information considered by the Agency in developing the proposed and final rules, including public comments and EPA's responses to the public comments received.

B. What is the Agency's authority for taking this action?

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III.

C. Applicability of general provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule.

Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to these SNURs must comply with the significant new use notice (SNUN) requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN and before the manufacture or processing for the significant new use can commence, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the *Federal Register*, a statement of EPA's findings.

III. Significant New Use Determination

A. Considerations for significant new use determinations

When the Agency issues an order under TSCA section 5(e), section 5(f)(4) requires that the Agency consider whether to promulgate a SNUR for any use not conforming to the restrictions of the TSCA Order or publish a statement describing the reasons for not initiating the rulemaking. TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing,

distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with possible uses of these chemical substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit.

B. Procedures for significant new uses claimed as CBI

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. When this rule was proposed on June 11, 2021 (86 FR 31239) (FRL-10022-56), EPA cross referenced 40 CFR 721.1725(b)(1), the procedures to deal with the situation where a specific significant new use is CBI, in order to apply it other SNURs where certain significant new uses have been claimed as CBI. Since the proposed rule, however, EPA has finalized amendments to 40 CFR 721.11 (87 FR 39756, July 5, 2022), which now provides a means by which bona fide submitters can determine whether their substance is subject to the SNUR and for EPA to disclose the confidential significant new use designations to a manufacturer or processor who has established a bona fide intent to manufacture or process a particular chemical substance. As such, EPA has removed the proposed references to 40 CFR 721.1725(b)(1) for SNURs that certain significant new uses have been claimed as CBI because the procedure in 40 CFR 721.11 now applies to all SNURs containing any CBI, including the significant new use.

Under these procedures a manufacturer or processor may request EPA to determine whether a specific use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the

chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in 40 CFR 721.11 into a single step to identify if a chemical substance is subject to part 721 and if a specific use would be a significant new use under the rule.

IV. Public Comments on Proposed Rule and EPA Responses

EPA received public comments from three identifying entities on the proposed rules. The Agency's responses are presented in the Response to Public Comments document that is available in the public docket for this rulemaking. EPA made a change to one of the proposed rules as described in the response to comments.

EPA made additional changes to the proposed rules because it inadvertently proposed incorrect terms in several SNURs. The revised language better reflects the language used in the underlying TSCA Orders for these chemical substances and these changes make the SNUR requirements consistent with those TSCA Orders. EPA received no comments on these requirements. For the SNURs for P-18-327 at 721.11588, P-18-218 at 721.11581, P-18-217 at 721.11580, and P-18-178 at 721.11579, EPA changed the language in paragraph (a)(1) exempting SNUR requirements from "completely reacted (cured)" to "completely entrained," which more accurately reflects the exemption language in the underlying TSCA Orders. For the SNURs for P-16-424 at 721.11574 and P-20-42 at 721.11601, EPA removed the proposed reporting requirement specified at 721.72(g)(2)(iv). This would have required the inclusion of the term "use respiratory protection" in hazard communication materials; however, this requirement was not in the underlying TSCA Orders for these two chemical substances. For the SNUR for P-20-42 at 721.11601, EPA added the reporting requirement specified at 721.72(f). This allows persons subject to the SNUR to use any existing hazard communication program that

meets the requirements of the SNUR. The underlying TSCA Order for this chemical substance contains this requirement.

V. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for chemical substances in 40 CFR part 721, subpart E. In Unit IV. of the proposed SNURs, EPA provided the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as confidential business information (CBI)).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Effective date of and basis for the TSCA Order.
- Potentially Useful Information. This is information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substances if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR.
- CFR citation assigned in the regulatory text section of these rules.

The regulatory text section of these rules specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the rules, may be claimed as CBI.

These final rules include PMN substances that are subject to orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). Those TSCA Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The final SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA Order usually requires that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL). The comprehensive NCELS provisions in TSCA Orders include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. No comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELS as an alternative to the 40 CFR 721.63 respirator requirements may request to do so under 40 CFR 721.30. EPA expects that persons whose 40 CFR 721.30 requests to use the NCELS approach for SNURs that are approved by EPA will be required to comply with NCELS provisions that are comparable to those contained in the corresponding TSCA Order.

VI. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs and as further discussed in Unit IV. of the proposed rules, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. Based on such findings, TSCA Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. As a general matter, EPA believes it is necessary to follow TSCA Orders with a SNUR that identifies the absence of those protective measures as significant new uses to ensure that all manufacturers and processors – not just the original submitter – are held to the same standard.

B. Objectives

EPA is issuing these SNURs because the Agency wants to

- Receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- Have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use; and
- Be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under TSCA section 5(a)(3)(C) that significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <https://www.epa.gov/tsca-inventory>.

VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted, EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this rule are added to the TSCA Inventory, EPA

recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA Orders have been issued for all the chemical substances that are the subject of this rule, and the PMN submitters are prohibited by the TSCA Orders from undertaking activities which will be designated as significant new uses. The identities of many of the chemical substances subject to this rule have been claimed as confidential (per 40 CFR 720.85). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

Furthermore, EPA designated the publication dates of the proposed rules (see Unit II.) as the cutoff dates for determining whether the new uses are ongoing. The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the final rule.

In the unlikely event that a person began commercial manufacture or processing of the chemical substances for a significant new use identified as of the abovementioned dates, that person will have to cease any such activity upon the effective date of the final rule. To resume their activities, that person would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

VIII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, TSCA Order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, TSCA Order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to them or reasonably

ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. of the proposed rule lists potentially useful information for all SNURs listed in this document. Descriptions are provided for informational purposes. The information identified in Unit IV. of the proposed rule will be potentially useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the information on the substance.

EPA strongly encourages persons, before performing any testing, to consult with the Agency. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit <https://www.epa.gov/assessing-and-managing-chemicals-under-tscs/alternative-test-methods-and-strategies-reduce>.

The potentially useful information identified in Unit IV. of the proposed rule may not be the only means of addressing the potential risks of the chemical substance associated with the designated significant new uses. However, submitting a SNUN without any test data or other information may increase the likelihood that EPA will take action under TSCA sections 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.

- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analyses are available in each docket listed in Unit II.

XI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

This action establishes SNURs for several new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval

under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The information collection requirements associated with SNURs have already been approved by OMB pursuant to the PRA under OMB control number 2070-0012 (EPA ICR No. 574). This rule does not impose any burden requiring additional OMB approval.

The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. The Information Collection Request (ICR) covering the SNUR activities was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is “good cause” under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

C. Regulatory Flexibility Act (RFA)

Pursuant to the RFA section 605(b) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these SNURs would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a “significant new use.” Because these uses are “new,” based on all information currently available to EPA, EPA has concluded that no small or large entities presently engage in such

activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was 10 in Federal fiscal year (FY) FY2016, 14 in FY2017, 16 in FY2018, five in FY2019, seven in FY2020, and 13 in FY2021, only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$19,020 to \$3,330. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$11,164 for qualifying small firms. Therefore, the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the *Federal Register* of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132: Federalism

This action will not have a substantial direct effect on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities

among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination with Indian Tribe Governments

This action does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This action does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children. EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards subject to NTTAA section 12(d) (15 U.S.C. 272 note).

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority

Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report containing this rule and other required information to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Administrative practice and procedure, Chemicals, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements.

40 CFR Part 725

Administrative practice and procedure, Biologics, Chemicals, Environmental protection, Hazardous substances, Imports, Labeling, Microorganisms, Occupational safety and health, Reporting and recordkeeping requirements.

Dated: November 17, 2022.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, for the reasons stated in the preamble, 40 CFR chapter I is amended as follows:

PART 9--OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 et seq., 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a; 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 et seq., 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, amend the table by adding in numerical order entries for §§ 721.11571 through 721.11602 under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

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40 CFR citation	OMB control No.
* * * * *	* * * * *
Significant New Uses of Chemical Substances	
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721.11571	2070-0012
721.11572	2070-0012
721.11573	2070-0012
721.11574	2070-0012
721.11575	2070-0012
721.11576	2070-0012
721.11577	2070-0012
721.11578	2070-0012
721.11579	2070-0012
721.11580	2070-0012
721.11581	2070-0012
721.11582	2070-0012
721.11583	2070-0012
721.11584	2070-0012
721.11585	2070-0012
721.11586	2070-0012
721.11587	2070-0012

721.11588	2070-0012
721.11589	2070-0012
721.11590	2070-0012
721.11591	2070-0012
721.11592	2070-0012
721.11593	2070-0012
721.11594	2070-0012
721.11595	2070-0012
721.11596	2070-0012
721.11597	2070-0012
721.11598	2070-0012
721.11599	2070-0012
721.11600	2070-0012
721.11601	2070-0012
721.11602	2070-0012
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PART 721--SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

Subpart E Significant New Uses for Specific Chemical Substances

4. Add §§ 721.11571 through 721.11602 in numerical order to subpart E to read as follows:

Sec.

* * * *

721.11571 Hindered amine alkyl ester compounds (generic).
721.11572 N-alkyl-dialkylpiperidine (generic).
721.11573 Tetraalkylpiperidinium halide (generic).
721.11574 Tetraalkylpiperidinium hydroxide (generic).
721.11575 Amidoamino quaternary ammonium salt (generic).
721.11576 Tri alkyl, mono alkoxy, fatty acid ester, ammonium salt (generic).
721.11577 Benzenediamine, ar-chloro-ar, ar-diethyl-ar-methyl-.
721.11578 1,4-benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear.
721.11579 Dialkyltin dialkylcarboxylate (generic).
721.11580 Alkyltin dodecylthioester (generic).
721.11581 Alkyltin tetradecylthioester (generic).
721.11582 Undecanol, branched.
721.11583 Hydroxy alkanoic acid, compds. with aminoalkoxyalcohol-epoxy polymer-alkanolamine reaction products (generic).
721.11584 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with ethyleneamine, 2-(chloromethyl)oxirane, 2-[[4-(1,1-dimethylethyl)phenoxy]methyl]oxirane, 2,2'-[1,6-

hexanediylbis(oxyethylene)]bis[oxirane], 4,4'-(1-methylethylidene)bis[phenol], alkyl ether amine, and 2-[(2-methylphenoxyethyl)oxirane (generic).

721.11585 Benzenepropanoic acid, 3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxy-, 2,2-bis(hydroxymethyl)butyl ester.

721.11586 1-Octadecanaminium, N,N-dimethyl-N-[3-(triethoxysilyl)propyl]-, chloride (1:1).

721.11587 2-Propenoic acid, 2-methyl-, 3-methyl-3-buten-1-yl ester.

721.11588 Mixed metal oxide (generic).

721.11589 Amines, polyethylenepoly-, triethylenetetramine fraction, polymers with guanidine hydrochloride (1:1).

721.11590 Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 3,6,9,12-tetraoxatetradeca-1, 13-diene, glycidyl ether.

721.11591 1,4-Benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester.

721.11592 Poly(oxy-1,2-ethanediyl), .alpha.-nonyl-.omega.-hydroxy-, branched and linear.

721.11593 1-Butanamine, N-butyl-N-[(triethoxysilyl)methyl]-.

721.11594 Alkenylamide (generic).

721.11595 Isoalkylaminium, N-isoalkyl-, -N, N-dimethyl chloride (generic).

721.11596 Aldehyde, polymer with mixed alkane polyamines, 2,2'-[1,4-alkanediylbis(oxyalkylene)]bis[oxirane], 2-(alkoxyalkyloxirane, 4,4'-(1-alkylidene)bis[phenol], 2,2'-[(1-alkylidene)bis(4,1-alkyleneoxyalkylene)]bis[oxirane] and 2-(aryloxyalkyl)oxirane, acetate (salt) (generic).

721.11597 Alkanedioic acid, compds. with substituted arylalkylamine-arylalcohol disubstituted alkane-the diglycidyl ether of a arylalcohol disubstituted alkane-epichlorohydrin-aldehyde-2,2'[(1-alkylidene)bis[4,1-aryleneoxy(alkyl-2,1-alkanediyl)oxyalkylene]]bis[oxirane]-alkanepolyamine polymer-1-[[2-[(2-aminoalkyl)amino]alkyl]amino]-3-aryloxy-2-alcohol reaction products (generic).

721.11598 Polyazaalkane with oxirane and methyloxirane, haloalkane (generic).

721.11599 Dibromoalkyl ether tetrabromobisphenol A (generic).

721.11600 Octanal, 7(or 8)-formyl-.

721.11601 Sulfonium, trisaryl-, 7,7-dialkyl-2-heteropolycyclic-1-alkanesulfonate (1:1) (generic).

721.11602 Alkenoic acid, polymer with (alkyl alkenyl) polyether (generic).

* * * * *

§ 721.11571 Hindered amine alkyl ester compounds (generic).

(a) *Chemical substance and significant new uses subject to reporting.* The chemical substance generically identified as hindered amine alkyl ester compounds (PMN P-16-167) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iv), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure of confinement of the operation, general and local ventilation) or administrative

control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets), gas/vapor (all substances in gas form), and combination gas/vapor and particulate (gas and liquid/solid physical states are present).

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(2)(i) through (v), (g)(3)(i) and (ii), (g)(4)(i) through (iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; respiratory complications; central nervous system effects; blood effects. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=1.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11572 N-alkyl-dialkylpiperidine (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as N-alkyl-dialkylpiperidine (PMN P-16-419) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3) through (6), (b), and (c). When determining which persons are likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include gas/vapor (all substances in the gas form). For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (v), (g)(3)(ii), (g)(4), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; serious eye damage; acute toxicity; specific target organ toxicity. For purposes of § 721.72(g)(4), notice to users: water release restrictions apply. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(h).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where $N=286$.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of §

721.185 apply to this section.

§ 721.11573 Tetraalkylpiperidinium halide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as tetraalkylpiperidinium halide (PMN P-16-423) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (b), and (c). When determining which persons are likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(ii), (g)(4), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), the substance may cause: acute toxicity; specific target organ toxicity; reproductive toxicity. For purposes of § 721.72(g)(4), notice to users: water release restrictions apply. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=20.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section

except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11574 Tetraalkylpiperidinium hydroxide (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as tetraalkylpiperidinium hydroxide (PMN P-16-424) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3), (b), and (c). When determining which persons are likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(ii), (g)(4), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; serious eye damage; acute toxicity; specific target organ toxicity; reproductive toxicity. For purposes of § 721.72(g)(4), notice to users: water release restrictions apply. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities*. Requirements as specified in §

721.80(k).

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where $N=20$.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11575 Amidoamino quaternary ammonium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as amidoamino quaternary ammonium salt (PMN P-17-235) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k).

(ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where $N=44$.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11576 Tri alkyl, mono alkoxy, fatty acid ester, ammonium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as tri alkyl, mono alkoxy, fatty acid ester, ammonium salt (PMN P-18-226) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=44.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11577 Benzenediamine, ar-chloro-ar, ar-diethyl-ar-methyl-

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as benzenediamine, ar-chloro-ar, ar-diethyl-ar-methyl- (PMN P-17-259; CAS No. 1616795-05-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=1.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section

except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11578 1,4-benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as 1,4-benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear (PMN P-18-43; CAS No. 2097734-13-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=2.

(ii) [Reserved]

(b) *Specific requirements*. The provision of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11579 Dialkyltin dialkylcarboxylate (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as dialkyltin dialkylcarboxylate (PMN P-18-178) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this

section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (6), and (c). When determining which persons are likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets).

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a stabilizer for PVC compounds.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (e), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11580 Alkyltin dodecylthioester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkyltin dodecylthioester (PMN P-18-217) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they

have been completely entrained.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3), and (c). When determining which persons are likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a stabilizer for PVC compounds.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (e), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section

§ 721.11581 Alkyltin tetradecylthioester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkyltin tetradecylthioester (PMN P-18-218) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3), and (c). When determining which persons are likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general, and local

ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a stabilizer for PVC compounds.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (e), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section

§ 721.11582 Undecanol, branched.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as undecanol, branched (PMN P-18-256; CAS No. 203743-00-4) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=4.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11583 Hydroxy alkanolic acid, compds. with aminoalkoxyalcohol-epoxy polymer-alkanolamine reaction products (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as hydroxy alkanolic acid, compds. with aminoalkoxyalcohol-epoxy polymer-alkanolamine reaction products (PMN P-18-283) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (f), (g)(1), (g)(2)(i) and (v), (g)(3)(ii), (g)(4)(iii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; skin sensitization; eye irritation; specific target organ toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11584 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with ethyleneamine, 2-(chloromethyl)oxirane, 2-[[4-(1,1-dimethylethyl)phenoxy]methyl]oxirane, 2,2'-[1,6-hexanediylbis(oxyethylene)]bis[oxirane], 4,4'-(1-methylethylidene)bis[phenol], alkyl ether amine, and 2-[(2-methylphenoxy methyl)oxirane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with ethyleneamine, 2-(chloromethyl)oxirane, 2-[[4-(1,1-dimethylethyl)phenoxy]methyl]oxirane, 2,2'-[1,6-hexanediylbis(oxyethylene)]bis[oxirane], 4,4'-(1-methylethylidene)bis[phenol], alkyl ether amine, and 2-[(2-methylphenoxy methyl)oxirane (PMN P-18-298) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the PMN substance for an application method that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=50.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11585 Benzenepropanoic acid, 3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxy-, 2,2-bis(hydroxymethyl)butyl ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as benzenepropanoic acid, 3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxy-, 2,2-bis(hydroxymethyl)butyl ester (PMN P-18-310; CAS No. 2101609-93-0) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include gas/vapor and particulate.

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.16 mg/m³ as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=1.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11586 1-Octadecanaminium, N,N-dimethyl-N-[3-(triethoxysilyl)propyl]-, chloride (1:1).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as 1-octadecanaminium, N,N-dimethyl-N-[3-(triethoxysilyl)propyl]-, chloride (1:1) (PMN P-18-318; CAS No. 62117-57-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(ii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; specific target organ toxicity. For purposes of § 721.72(e), the concentration is set at 1.0%. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a surface treatment for added lubricity and anti-static properties. It is a significant new use to use the substance in an application method that results in inhalation exposure to workers.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11587 2-Propenoic acid, 2-methyl-, 3-methyl-3-buten-1-yl ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-propenoic acid, 2-methyl-, 3-methyl-3-buten-1-yl ester (PMN P-18-323; CAS No. 156291-88-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF)

of at least 50. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets) and gas/vapor (all substances in the gas form).

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(2)(i) through (v), (g)(3)(i) and (ii), (g)(4)(i) through (iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; developmental effects; systemic effects; respiratory effects; skin sensitization; respiratory sensitization. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer use*. Requirements as specified in § 721.80(k).

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=98.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11588 Mixed metal oxide (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as mixed metal oxide (PMN P-18-327) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as

required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.1 mg/m³ as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

(ii) *Hazard communication.* Requirements as specified in §721.72(a) through (d), (f), (g)(1), (g)(2), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: cancer; skin sensitization; respiratory sensitization; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used. For purposes of § 721.72(g)(2), when using this substance: avoid skin contact, avoid breathing substance, avoid ingestion, use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.1 mg/m³, and use skin protection.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h)

are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11589 Amines, polyethylenepoly-, triethylenetetramine fraction, polymers with guanidine hydrochloride (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as amines, polyethylenepoly-, triethylenetetramine fraction, polymers with guanidine hydrochloride (1:1) (PMN P-18-347; CAS No. 1902936-67-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) and (v), (g)(3)(i) and (ii), (g)(4)(i), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin sensitization; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=2.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11590 Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 3,6,9,12-tetraoxatetradeca-1, 13-diene, glycidyl ether.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as phenol, 4,4'-(1-methylethylidene)bis-, polymer with 3,6,9,12-tetraoxatetradeca-1, 13-diene, glycidyl ether (PMN P-18-405; CAS No. 647028-24-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=1.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11591 1,4-Benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical

substance identified as 1,4-benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester (PMN P-19-36; CAS No. 25900-07-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure of confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=3.

(b) *Specific requirements.* The provisions of subpart A of this part may apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (e) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11592 Poly(oxy-1,2-ethanediyl), .alpha.-nonyl-.omega.-hydroxy-, branched and linear.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly(oxy-1,2-ethanediyl), .alpha.-nonyl-.omega.-hydroxy-, branched and

linear (PMN P-19-52; CAS No. 2242406-13-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3) through (6), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets). For purposes of § 721.63(b), the concentration is set at 1%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; respiratory complications; internal organ effects; eye corrosion. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer use.* It is a significant new use to use the substance where the concentration of the substance in the product formulation intended for distribution in commerce exceeds 1% by weight.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=34.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11593 1-Butanamine, N-butyl-N-[(triethoxysilyl)methyl]-.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as 1-butanamine, N-butyl-N-[(triethoxysilyl)methyl]- (PMN P-19-53; CAS No. 35501-23-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1) and (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f) and (o). It is a significant new use to process and use the substance other than in a liquid formulation.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (e), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11594 Alkenylamide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkenylamide (PMN P-19-77) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=4.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11595 Isoalkylaminium, N-isoalkyl, -N, N-dimethyl chloride (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as isoalkylaminium, N-isoalkyl, -N, N-dimethyl chloride (PMN P-19-131) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or destroyed (e.g., reacted to bind with clay).

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11596 Aldehyde, polymer with mixed alkane polyamines, 2,2'-[1,4-alkanediylbis(oxyalkylene)]bis[oxirane], 2-(alkoxyalkyloxirane, 4,4'-(1-alkylidene)bis[phenol], 2,2'-[(1-alkylidene)bis(4,1-alkyleneoxyalkylene)]bis[oxirane] and 2-(aryloxyalkyl)oxirane, acetate (salt) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as aldehyde, polymer with mixed alkane polyamines, 2,2'-[1,4-alkanediylbis(oxyalkylene)]bis[oxirane], 2-(alkoxyalkyloxirane, 4,4'-(1-alkylidene)bis[phenol], 2,2'-[(1-alkylidene)bis(4,1-alkyleneoxyalkylene)]bis[oxirane] and 2-(aryloxyalkyl)oxirane, acetate (salt) (PMN P-19-143) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured) or destroyed.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure to either the PMN substance or to formaldehyde.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11597 Alkanedioic acid, compds. with substituted arylalkylamine-arylalcohol disubstituted alkane-the diglycidyl ether of a arylalcohol disubstituted alkane-epichlorohydrin-aldehyde-2,2'[(1-alkylidene)bis[4,1-aryleneoxy(alkyl-2,1-alkanediyl)oxyalkylene]]bis[oxirane]-alkanepolyamine polymer-1-[[2-[(2-aminoalkyl)amino]alkyl]amino]-3-aryloxy-2-alcohol reaction products (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkanedioic acid, compds. with substituted arylalkylamine-arylalcohol disubstituted alkane-the diglycidyl ether of a arylalcohol disubstituted alkane-epichlorohydrin-aldehyde-2,2'[(1-alkylidene)bis[4,1-aryleneoxy(alkyl-2,1-alkanediyl)oxyalkylene]]bis[oxirane]-alkanepolyamine polymer-1-[[2-[(2-aminoalkyl)amino]alkyl]amino]-3-aryloxy-2-alcohol reaction products (PMN P-19-144) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured) or destroyed.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure to either the PMN substance or to formaldehyde.

(ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=1.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11598 Polyazaalkane with oxirane and methyloxirane, haloalkane (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as polyazaalkane with oxirane and methyloxirane, haloalkane (PMN P-19-145) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: reproductive toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities*. It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(iii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=26.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), (f) through (h), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

§ 721.11599 Dibromoalkyl ether tetrabromobisphenol A (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as dibromoalkyl ether tetrabromobisphenol A (PMN P-19-153) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: eye irritation; carcinogenicity; reproductive toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water*. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11600 Octanal, 7(or 8)-formyl-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as octanal, 7(or 8)-formyl- (PMN P-20-29; CAS No. 1607842-40-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=17.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11601 Sulfonium, trisaryl-, 7, 7-dialkyl-2-heteropolycyclic-1-alkanesulfonate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as sulfonium, trisaryl-, 7, 7-dialkyl-2-heteropolycyclic-1-alkanesulfonate (1:1) (PMN P-20-42) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during the photolithographic process) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the PMN substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the PMN substance in any way that generates a dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the PMN substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11602 Alkenoic acid, polymer with (alkyl alkenyl) polyether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkenoic acid, polymer with (alkyl alkenyl) polyether (PMN P-20-104) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in a manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=75.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

* * * * *

PART 725-- REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS

3. The authority citation for part 725 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625.

4. Add § 725.1081 to read as follows:

§ 725.1081 *Trichoderma reesei* modified (generic).

(a) *Microorganism and significant new uses subject to reporting.* (1) The genetically modified microorganism generically identified as *Trichoderma reesei* modified (MCAN J-16-26)

is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2)(i) It is a significant new use to manufacture, process, or use the microorganism other than in a fermentation system that meets all of the following conditions:

(A) Enzyme production occurs by submerged fermentation (i.e., for enzyme production, growth of the microorganism occurs beneath the surface of the liquid growth medium); and

(B) Any fermentation of solid plant material or insoluble substrate to which *Trichoderma reesei* fermentation broth is added after the standard industrial fermentation is completed is initiated only after the inactivation of the microorganism as delineated in § 725.422(d).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart L of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 725.950(b)(2) through (4) are applicable to manufacturers and processors of this microorganism.

(2) *Modification or revocation of certain notification requirements.* The provisions of § 725.984 apply to this section.

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